REMARKS

Claims 40 to 51 are pending in this application. As will be discussed further below, the first page of the Office Action indicates that claims 38 and 41 to 44 have been found to be allowable. On the other hand, at the bottom of page 8, the Examiner indicates that claims 39 and 41 to 44 have been found to be allowable. Applicants have amended the claims on the assumption that the Examiner intended to indicate that both claims 38 and 39 are allowable, and have amended the claims accordingly.

In the present instance, the compounds claims of Restriction Group II (the elected Group), are original claims 35 to 46.

At page 2 of the Office Action, the Examiner has made the Restriction Requirement final. The Examiner states:

> The requirement is still deemed proper and is therefore made FINAL. Claims 15-46 have been examined to the extent they read on the elected invention and specie.
>
> As the elected specie, 17β-hydroxy-16-(pyrimidin-5-ylmethylidene)-4-methyl-4-aza-5α-androst-1-en-3-one, is found free of art, the search is extended to all the compounds of formula 1.

Applicants have replaced claim 38 with "(New)" claim 47, which incorporates the limitations of claims 38 into base claim 35. Accordingly, "(New)" claim 47 is fully supported by original 38.

Applicants have replaced claim 39 with "(New)" claim 48, which incorporates the limitations of claim 39 into base claim 35. Accordingly, "(New)" claim 48 is fully supported by original claim 39.

Applicants have amended claims 40 to indicate the replacement of reference claim 39 with "(New)" claim 48.

Applicants have replaced claim 42 with "(New)" claim 49, which incorporates the limitations of claim 42 into base claim 35. Accordingly, "(New)" claim 49 is fully supported by original 42.

At the top of page 3 of the Office Action, the Examiner rejects "Use" claims 30-32 under 35 USC 101 and 112. Applicants made no admissions with regard to these rejections and specifically reserve the right to prosecute claims 30-32 in a continuing or divisional application. Nonetheless, in order to advance the prosecution of this application, applicants have cancelled claims 30-32.

At the middle of page 3, the Examiner rejects claims 23-27, 29 and 33-34 under 35 USC 112, second paragraph. The Examiner states:

> The limitations "estrogen derivative", "progestin derivative", "parathyroid hormone or analog", "an inhibitor of BMP antagonism", " prostaglandin derivative", "vitamin D derivative", "vitamin K derivative" recited in claims 23-27, 29, 33-34 render the claims indefinite because it is not clear what compounds are encompassed by the claims. The metes and bounds of the claims are therefore not clear. For example, PTH "partial sequences", recited in claim 24, is not clear what sequence be encompassed by such limitations.
>
> Claims 23-27, 29, and 33-34 contain the trademark/trade name "C1-680, C1-628...U-100A", "EM-800", EM-652, TSE 424", "EB1089", "KH1060", ED71. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with requirements of 35 U.S.C. 112, second paragraph. See EX parte Simpson, 218 SUPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe various secondary compounds and, accordingly, the identification/description is indefinite.

Bridging pages 5 and 6, the Examiner rejects claims 15-28 under 35 USC 112, first paragraph. The Examiner states:

> In the instant case, the burden of enabling the preventing the formation of osteoporosis, osteopenia, sarcopenia, and frailty requires appropriate screening testing, subsequent data compilation, and finally appropriate data analysis, to assess and properly enable one skill in the art whether wrinkles are prevented from formation in a patient. For example, the specification must provide adequate guidance whether osteoporosis, osteopenia, sarcopenia, and frailty can be prevented from forming in a patient or in this case, a mammal, once the composition is administered to a subject susceptible to develop osteoporosis, osteopenia, sarcopenia, and frailty.
>
> Moreover, the specification must provide direct evidence associating the claimed prevention to the composition applied. The burden of showing preventative properties is greater than that of enabling a treatment, because one of ordinary skill in the art must not only show competent screening of those subjects susceptible to such conditions, but also show that the efficacy of a preventative method is directly caused by apply or administering the instantly claimed composition to the susceptible subjects."

Applicants make no admissions with regard to these 112 rejections and specifically reserve the right to prosecute cancelled or unclaimed subject matter in a continuing or divisional application. Nonetheless, applicants have cancelled these claims in order to advance the prosecution of this application.

Beginning at the bottom of page 6, the examiner rejects claims 15-37, 39-40 and 45-46 under 35 ISC 103(a) as being unpatentable over (WO98/25622, WO98/25623, US 5,945,412 in view of US 5,693,809. The Examiner states:

> '622 teaches 5-α reductase inhibitors, which are structurally similar to the herein claimed compounds, with optional secondary compounds are useful in treating osteosprosis (See page 19, lne 25 – page 25, line 24). The secondary compounds can be herein claimed estrogen derivatives and bisphosphonates.
>
> '623 teaches 5-α reductase inhibitor finesteride with optional secondary compounds are useful in treating osteoporosis (See page 10 – page 19 example). The secondary compounds can be the herein claimed estrogen derivatives and bisphosphonates such as alendronate (See page 14, line 23 for example).
>
> '412 teaches 5-α reductase inhibitor compounds, which are structurally similar to the herein claimed compounds, with optional secondary compounds are useful in treating osteoporosis (see col. 3, line 4 – line 29). The secondary

compounds can be the herein claimed estrogen derivatives and bisphosphonates (see col. 16, line 36 – col. 19, line 58).

The references do not expressly teach the herein claimed compounds of formula 1 with optional alendronate or other secondary compounds herein as useful in treating osteoporosis.

'809 teaches the herein claimed aza-androstene compounds when A is OH (see formula 11A), Z is α-hydrogen and β-hydrogen, T1 and T2 is hydrogen and alkyl respectively (See col. 2, line 50 – col. 4, line 15, example). "809 also teaches the compounds are 5α-reductase inhibitors (See col. 2, lines 37-45).

Applicants make no admissions with regard to this rejection and specifically reserve the right to prosecute cancelled or unclaimed subject matter in a continuing or divisional application. Nonetheless, in order to advance the prosecution of this application, applicants have cancelled the above described subject matter from their application.

Having addressed the outstanding issues, Applicants respectfully request early examination and allowance of the claims. The Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of this application.

Respectfully submitted,

By _____

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